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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/054,760 | 11/13/2001 | Thomas Wiggins | 24499-530 | 6361 |

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EXAMINER

SINES, BRIAN J

ART UNIT PAPER NUMBER

1743

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/054,760 | Applicant(s) WIGGINS ET AL. | |
| | Examiner Brian J. Sines | Art Unit 1743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-47 is/are pending in the application.
 4a) Of the above claim(s) 28-45 is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-27, 46 and 47 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 13 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____. |
|--|--|

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DETAILED ACTION

Election/Restrictions

Applicant's election of group I, claims 1 – 27, 46 and 47 in the response filed 11/20/2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 28 – 45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitation "control fluid" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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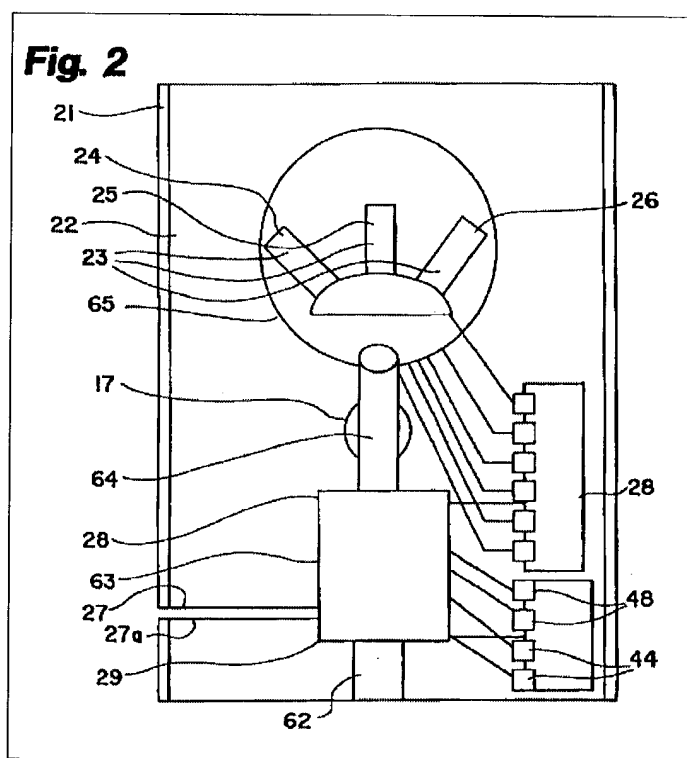
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

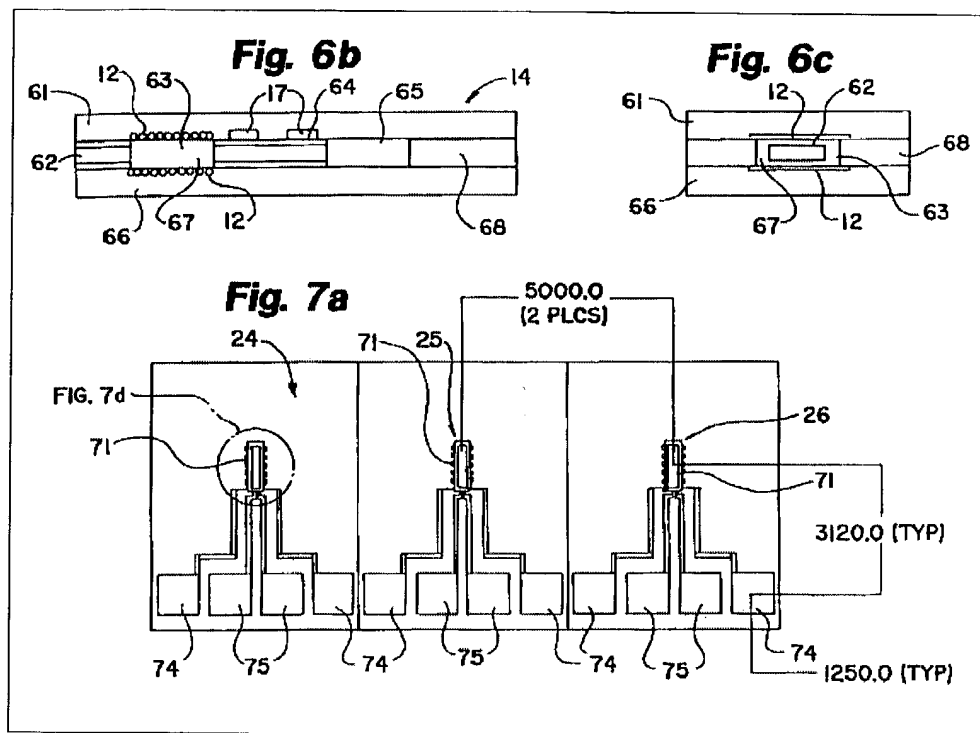
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furcht *et al.* (U.S. Pat. No. 6,054,277 A) in view of Wolk *et al.* (U.S. Pat. No. 6,620,625 B2). Regarding claims 1, 4, 7 and 8, Furcht *et al.* teach a microfluidic apparatus (10) comprising: an interaction cell or chamber (65); a fluid control means (64); and a plurality of microcantilevers (71) (see col. 10, lines 39 – 67; col. 11, lines 1 – 17; figures 2 & 7a). Furcht *et al.* do not specifically teach the incorporation of a plurality of interaction cells or detection chambers (65). However, the utilization of microfluidic screening systems comprising a plurality of test or detection chambers or wells in a multiwell plate, or test samples located on discrete areas of a substrate, for analyzing a plurality of test samples are notoriously well known in the art, as evidenced by Wolk

et al., for example (see MPEP § 2144.03). Furthermore, the Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of a person of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a *plurality* of interaction cells with the apparatus of Furcht *et al.* in order to facilitate the effective screening of a plurality of test samples. Regarding claim 5, Furcht *et al.* teach the use of computer software in controlling the apparatus, thereby enabling for the automatic or robotic control of fluids during operation (see col. 6, lines 6 – 17).



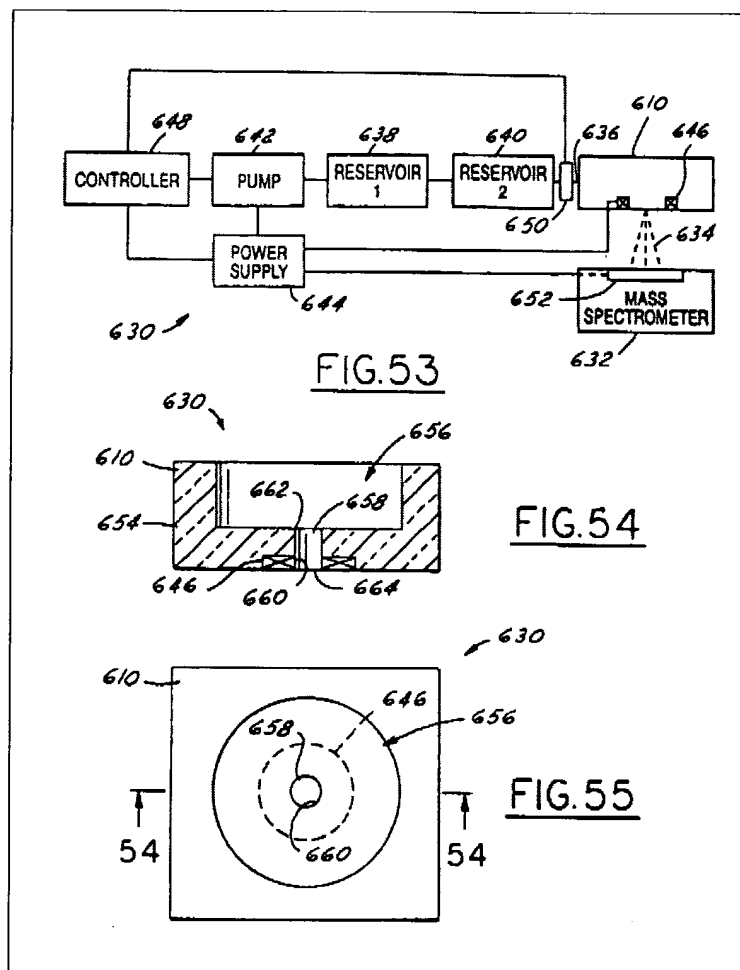


Regarding claims 2, 3, 6, 9 and 10, the recitation that the claimed apparatus is either disposable or reusable, or that it is operated manually, is considered a process or intended use limitation, which does not further delineate the structure of the claimed apparatus from that of the prior art. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. These recited process or intended use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA

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1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).

2. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Furcht *et al.* in view of Wolk *et al.*, as applied to claims 1 – 10 above, and further in view of Pfof *et al.* (U.S. Pat. No. 6,485,690 B1). Furcht *et al.* do not specifically teach the incorporation of an interaction cell further comprising at least one outlet, whereby fluid may flow out of the cell. However, Pfof *et al.* do teach a multiple fluid sample distribution system for high-throughput biological assays. The apparatus disclosed by Pfof *et al.* can be used for synthesizing arrays of DNA, and for DNA sample processing and testing (see col. 5, lines 38 – 49). Pfof *et al.* teach that the wells (656) of their disclosed apparatus comprise an outlet (658) (see col. 22, lines 42 – 62; figures 54 & 55).



The applicant is advised that the Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Since Pfoest *et al.* effectively demonstrate the utilization of such a fluid distribution system in chemical diagnostic assay apparatus, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating such a system with the analytical apparatus as taught by Furcht *et al.* in view of Wolk *et al.* Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the fluid distribution system,

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as taught by Pfohl *et al.*, with the apparatus as taught by Furcht *et al.* in view of Wolk *et al.*, in order to facilitate effective sample analysis and processing.

3. Claims 12 – 27, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furcht *et al.* in view of Wolk *et al.*, and further in view of Pfohl *et al.* Regarding claims 12, 13, 15 – 19, 25 – 27, 46 and 47, Furcht *et al.* teach a microfluidic apparatus (10) comprising: an interaction cell or chamber (65); a fluid control means (64); and a plurality of microcantilevers (71) (see col. 10, lines 39 – 67; col. 11, lines 1 – 17; figures 2 & 7a). Furcht *et al.* do not specifically teach the incorporation of a plurality of interaction cells or detection chambers (65). However, the utilization of microfluidic screening systems comprising a plurality of test or detection chambers or wells in a multiwell plate, or test samples located on discrete areas of a substrate, for analyzing a plurality of test samples are notoriously well known in the art, as evidenced by Wolk *et al.*, for example (see MPEP § 2144.03). Furthermore, the Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of a person of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a plurality of interaction cells with the apparatus of Furcht *et al.* in order to facilitate the effective screening of a plurality of test samples. Furcht *et al.* teach the use of computer software in controlling the apparatus, thereby enabling for the automatic or robotic control of fluids during operation (see col. 6, lines 6 – 17). Furcht *et al.* do not specifically teach the incorporation of a fluid distribution system, which would facilitate sample processing and testing in an apparatus comprising a plurality of interaction cells or detection chambers. However, Pfohl *et al.* do teach a multiple fluid sample distribution system for high-throughput biological assays. The apparatus

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disclosed by Pfof *et al.* can be used for synthesizing arrays of DNA, and for DNA sample processing and testing (see col. 5, lines 38 – 49). Pfof *et al.* teach that the sizes of the micro-sized channels, apertures and valves are adjusted to optimize fluid distribution and channel filling (see Abstract). Pfof *et al.* teach that the apparatus further comprises pumping mechanisms (40 & 42), microvalves (28 & 32), microchannels and passageways, *etc.*, for facilitating effective fluid transfer and distribution within the apparatus (see Description of the Preferred Embodiment section). Pfof *et al.* teach that the apparatus, which can have a modular configuration, provides for temperature control (see col. 6, lines 22 – 32; col. 8, lines 55 – 58).

The applicant is advised that the Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Since Pfof *et al.* effectively demonstrate the utilization of such a fluid distribution system in chemical diagnostic assay apparatus, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success in incorporating such a system with the analytical apparatus as taught by Furcht *et al.* in view of Wolk *et al.* Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the fluid distribution system, as taught by Pfof *et al.*, with the apparatus as taught by Furcht *et al.* in view of Wolk *et al.*, in order to facilitate effective sample analysis and processing.

Regarding claims 14 and 20 – 24, these claims are considered process or intended use limitations, which do not further delineate the structure of the claimed apparatus from that of the prior art. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in

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determining the patentability of the apparatus itself. These recited process or intended use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Porter *et al.* teach an apparatus and method for sensing chemical or biological analytes using a microcantilever.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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Technology Center 1700